

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

NOETIC SPECIALTY INSURANCE	§	
COMPANY n/k/a PROASSURANCE	§	
SPECIALTY INSURANCE COMPANY	§	
d/b/a NOETIC SPECIAL INSURANCE,	§	
	§	
<i>Plaintiff,</i>	§	CIVIL ACTION
	§	NO. 22-2398
v.	§	
	§	
B. BRAUN MEDICAL, INC., <i>et al.</i> ,	§	
	§	
<i>Defendants.</i>	§	

MEMORANDUM OPINION

SCHMEHL, J. /s/ JLS

OCTOBER 28, 2024

This civil action stems from a dispute over an insurance provider’s alleged obligations to defend and indemnify their insured in underlying toxic-tort litigation. Now pending before the Court are the parties’ competing motions for judgment on the pleadings. The motions present the question of whether pollution-exclusion clauses in Products/Completed Operations Liability insurance policies relieve an insurer of its obligation to defend its insured in the underlying actions. As explained below, the Court concludes that the pollution-exclusion clauses apply, permitting the insurer to decline to defend the underlying actions. The insurance provider’s motion for judgment on the pleadings is therefore granted.

I

A

The events giving rise to this litigation are as follows: The Defendants operate a medical-device manufacturing plant in the city of Allentown, Pennsylvania. In December 2019, a class-

action lawsuit was filed against Defendant B. Braun Medical, Inc. It alleged that B. Braun Medical, Inc. exposed the residents of Allentown to ethylene oxide (“EtO”), a gaseous, carcinogenic chemical used in Braun’s sterilization processes. In 2021, while that action advanced, an avalanche of individual civil actions hit Defendants B. Braun Medical Inc., B. Braun of America Inc., B. Braun CeGat, LLC, and B. Braun Interventional Systems Inc. (collectively, “Braun”)—all making allegations against Braun substantially similar to those asserted in the initial class-action complaint.

Braun tendered the defense of those lawsuits to their insurer, Plaintiff Noetic Specialty Insurance Company (“Noetic”). Braun claims that Noetic owes Braun a duty to defend and indemnify under the following three Products/Completed Operations Liability insurance policies, which vary in their periods of coverage, but are otherwise essentially verbatim:

- (1) Policy No. N18PA380025—December 31, 2018, to December 31, 2019;
- (2) Policy No. N20PA380025—December 31, 2020, to December 31, 2021; and
- (3) Policy No. N21PA380027—December 31, 2021, to December 31, 2022.

Noetic disagrees with Braun’s conclusion and has initiated a declaratory-judgment action to resolve the dispute. Noetic asks that the Court declare that Noetic has no duty to defend or indemnify Braun pursuant to the policies’ pollution-exclusion clauses. Braun, in response, has counterclaimed, seeking a contrary declaration, and asserting two breach-of-contract counts and a bad-faith count under 42 Pa. Cons. Stat. § 8371. Both parties have moved for judgment on the pleadings.

B

The parties concur that the insurance policies provide, in relevant part, as follows:

SECTION 1 – COVERAGES

A. PRODUCTS/COMPLETED OPERATIONS BODILY INJURY AND PROPERTY DAMAGE LIABILITY

1. Insuring Agreement

a. We will pay those sums, in excess of the **Deductible**, that the **Insured** becomes legally obligated to pay as **Damages** because of **Bodily Injury** or **Property Damage** to which this insurance applies. This insurance applies only if:

(1) the **Bodily Injury** or **Property Damage** is included within the **Products/Completed Operations Hazard**;

(2) the **Bodily Injury** or **Property Damage** is caused by an **Occurrence** that takes place in the **Coverage Territory**;

(3) the **Bodily Injury** or **Property Damage** did not occur before the **Retroactive Date**, if any, shown in the Declarations or after the end of the policy period, provided that, any **Bodily Injury** or **Property Damage** that commences before the **Retroactive Date** and continues after the **Retroactive Date** will be deemed to have occurred before the **Retroactive Date**;

(4) a **Claim** because of **Bodily Injury** or **Property Damage** is first made against any **Insured** during the policy period or any Extended Reporting Period and is reported to us as soon as reasonably possible; and

(5) the **Claim** did not arise out of a **Serious Adverse Event** that any **Insured** knew about prior to the effective date of this policy, but did not report to us or another insurer prior to such effective date, or disclose on the Application for this insurance.

...

SECTION IV – EXCLUSIONS

This Insurance does not apply to:

...

13. Pollution

a. **Bodily Injury** or **Property Damage** which would not have occurred but for the actual, alleged, or threatened discharge, dispersal, seepage, migration, release, or escape of **Pollutants** at any time.

b. Any loss, cost, or expense arising out of any:

(1) Request, demand, or order or statutory or regulatory requirement that any **Insured** or others test for, monitor, clean up, remove, contain, treat, detoxify, neutralize, or in any way respond to, or assess the effects of **Pollutants**; or

(2) **Claim** by or on behalf of a governmental authority because of testing for, monitoring, cleaning up, removing, containing, treating, detoxifying, neutralizing, or in any way responding to, or assessing the effects of **Pollutants**.

c. This exclusion does not apply:

(1) where **Your Product** or **Your Work** was cleared by any government health authority or regulatory body for marketing with a specific indication for medical, diagnostic, or therapeutic use; or

(2) to **Bodily Injury** or **Property Damage** arising out of heat, smoke, or fumes from a **Hostile Fire** unless that **Hostile Fire** occurred or originated at any premises, site, or location:

(a) which is or was at any time used by or for any **Insured** or others for the handling, storage, disposal, processing, or treatment of waste; or

(b) which any **Insured** or any contractors or subcontractors working directly or indirectly on any **Insured's** behalf are performing operations to test for, monitor, clean up, remove, contain, treat, detoxify, neutralize, or in any way respond to, or assess the effects of **Pollutants**.

...

SECTION VII – DEFINITIONS

...

3. **Bodily Injury** means:

a. Physical harm, sickness, or disease sustained by a person, including death resulting from any of these at any time; and

b. Any mental anguish, mental injury, disability, shock, fright or humiliation sustained by that person or by any relative of that person as a result of such physical harm, sickness, disease, or death.

...

43. Occurrence means an accident, including continuous or repeated exposure to substantially the same general harmful conditions.

...

45. Pollutants means any solid, liquid, gaseous, or thermal irritant or contaminant, including smoke, vapor, soot, fumes, acid, alkalis, chemicals, and waste. Waste includes materials to be recycled, reconditioned, or reclaimed.

46. Products/Completed Operations Hazard:

a. Includes:

(1) **Bodily Injury and Property Damage** occurring away from premises you own or rent and arising out of **Your Work or Your Product**;

(2) **Bodily Injury and Property Damage** arising on premises you own or rent, if such **Bodily Injury or Property Damage** arises out of **Your Product** while being used for its intended purpose;

(3) **Bodily Injury and Property Damage** arising while **Your Product** is still in your physical possession if such **Bodily Injury or Property Damage** arises out of **Your Product** while being used for its intended purpose;

(4) **Bodily Injury and Property Damage** arising out of products being rented, leased, loaned, or held for sale, demonstration or trial purposes by you; and

(5) **Bodily Injury and Property Damage** arising out of **Clinical Testing of Your Product**.

...

67. Your Product:

a. Means:

(1) Any **Medical Device, Drug, Biologic, In-vitro Diagnostic, Cosmetic, Soap, Nutraceutical, Dietary Supplement**, animal, other diagnostic or therapeutic products or processes, or any component thereof, other than real property, and, unless specifically

excluded, any other product(s) other than real property designed, developed, manufactured, sold, handled, or distributed by:

(a) You;

(b) Others trading under your name; or

(c) A person or organization whose business or assets you have acquired;

(2) Containers (other than vehicles), materials, technology, parts, or equipment furnished in connection with such goods or products; and

(3) Goods, products, or equipment leased, loaned, or held for sale, demonstration, or trial purposes.

b. Includes:

(1) **Warranties** or representations made at any time with respect to the fitness, quality, durability, performance, or use of **Your Product**; and

(2) The providing of or failure to provide consultation or educational services, training, advice, warnings, or instructions in the use and care of any products.

68. Your Work:

a. Means:

(1) Work or operations performed by you or on your behalf, and includes technology, materials, parts, or equipment furnished in connection with such work or operations, including mobile cadaver training laboratories.

b. Includes:

(1) **Warranties** or representations made at any time with respect to the fitness, quality, durability, performance, or use of **Your Work**; and

(2) The providing of or failure to provide consultation or educational services, training, advice, warnings, or instructions in **Your Work**.

**(3) Attending and observing medical or surgical procedures
or Grand Rounds.**

II

In analyzing a motion under Federal Rule of Civil Procedure 12(c), the Court will use the same standards that it uses in assessing a Rule 12(b)(6) motion. *Wolfington v. Reconstructive Orthopaedic Assocs. II PC*, 935 F.3d 187, 195 (3d Cir. 2019). That is, the Court will construe the “complaint, exhibits attached to the complaint, matters of public record, [and] undisputedly authentic documents if the complainant’s claims are based upon these documents,” in the light most favorable to the nonmoving party. *Id.* After so doing, the Court will only grant the motion if the movant clearly establishes that no material issues of fact remain and that they are entitled to judgment as a matter of law. *Id.* For today’s analysis, the Court will treat Noetic as the movant and Braun as the nonmovant.

III

A

The parties agree that Pennsylvania’s substantive law governs this diversity action. Under Pennsylvania law, “[a] court’s first step in a declaratory judgment action concerning insurance coverage is to determine the scope of the policy’s coverage.” *Gen. Accident Ins. Co. of Am. v. Allen*, 692 A.2d 1089, 1095 (Pa. 1997). In reaching that determination, a court must construe the policy as a whole and “in accordance with the plain meaning of terms.” *Am. Auto. Ins. Co. v. Murray*, 658 F.3d 311, 320 (3d Cir. 2011) (applying Pennsylvania law). “[I]f possible, a court should interpret the policy so as to avoid ambiguities and give effect to all of its provisions.” *Id.* at 321 (quoting *Med. Protective Co. v. Watkins*, 198 F.3d 100, 103 (3d Cir. 1999)). That said, “if the contract’s terms are reasonably susceptible to more than one interpretation, then they must be

regarded as ambiguous.” *Id.* An ambiguous provision “‘must be construed against the insurer and in favor of the insured.’” *Id.* (quoting *Med. Protective Co.*, 198 F.3d at 104).

Once a court determines the scope of coverage, it then “examine[s] the complaint in the underlying action to ascertain if it triggers coverage.” *Allen*, 692 A.2d at 1095. “Whether a claim is ‘potentially covered is answered by comparing the four corners of the insurance contract to the four corners of the complaint.’” *Erie Ins. Exch. v. Moore*, 228 A.3d 258, 265 (Pa. 2020) (quoting *Am. & Foreign Ins. Co. v. Jerry’s Sport Ctr., Inc.*, 2 A.3d 526, 541 (Pa. 2010)). A court must accept the factual allegations of the underlying complaint against the insured as true and liberally construe them in favor of the insured. *Firemen’s Ins. Co. of Washington, D.C. v. Tray-Pak Corp.*, 130 F. Supp. 3d 973, 980 (E.D. Pa. 2015). “If, after conducting this analysis, [a court] conclude[s] even ‘a single claim in [a] multiclaim lawsuit is potentially covered, the insurer must defend all claims until there is no possibility that the underlying plaintiff could recover on a covered claim.’” *State Farm Fire & Cas. Co. v. Motta*, 356 F. Supp. 3d 457, 462 (E.D. Pa. 2018) (quoting *Frog, Switch & Mfg. Co. v. Travelers Ins. Co.*, 193 F.3d 742, 746 (3d Cir. 1999)).

B

Noetic asks that the Court resolve this dispute based upon the policies’ pollution-exclusion clauses. Noetic asserts that since the underlying complaints allege that EtO is effectively a pollutant under the policies, the pollution exclusions apply, relieving Noetic of any duty to defend or indemnify Braun in the underlying actions. Braun asserts that—since Noetic bears the burden of proving the applicability of a policy exclusion—Noetic cannot, as a matter of law, carry its burden by relying merely on the averments in the underlying complaints to establish that EtO is a “pollutant.” Instead, Braun claims that Noetic must demonstrate, with some extrinsic evidence, that EtO meets the policies’ “pollutant” standard. In support of this proposition, Braun cites to:

Gamble Farm Inn, Inc. v. Selective Ins. Co., 656 A.2d 142 (Pa. Super. Ct. 1995); *Madison Const. Co. v. Harleysville Mut. Ins. Co.*, 735 A.2d 100 (Pa. 1999); *Mun. of Mt. Lebanon v. Reliance Ins. Co.*, 778 A.2d 1228 (Pa. Super. Ct. 2001); *Lititz Mut. Ins. Co. v. Steely*, 785 A.2d 975 (Pa. 2001); *Wagner v. Erie Ins. Co.*, 801 A.2d 1226 (Pa. Super. Ct. 2002); *Colony Ins. Co. v. Zena Associates, LLC*, No. 12-4305, 2012 WL 12897100, at *1 (E.D. Pa. Dec. 17, 2012); *A. Cas. Ins. Co. v. Zymblosky*, No. 14-1021, 2015 WL 507203, at *1 (M.D. Pa. Feb. 6, 2015); and *Neth. Ins. Co. v. Butler Area Sch. Dist.*, 256 F. Supp. 3d 600 (W.D. Pa. 2017).

After carefully reviewing those decisions, the Court concludes that they do not, individually or collectively, hold that an insurer can never satisfy its burden of proving that a policy exclusion applies by simply relying on averments in the underlying complaints. The Court's conclusion is supported by the fact that this very Court has ruled that an insurer can demonstrate the applicability of a pollution exclusion based solely on the underlying complaints several times before. *See, e.g., Mark I Restoration SVC v. Assurance Co. of Am.*, 248 F. Supp. 2d 397, 405 (E.D. Pa. 2003), *aff'd*, 112 Fed. Appx. 153 (3d Cir. 2004) (unpublished); *Hyde Athletic Industries, Inc. v. Contl. Cas. Co.*, 969 F. Supp. 289, 296-97 (E.D. Pa. 1997) ("The nature of the underlying claims clearly triggers the pollution exclusion clause."); *Travelers Prop. Cas. Co. of Am. v. Chubb Custom Ins. Co.*, 864 F. Supp. 2d 301, 313 (E.D. Pa. 2012) ("The Court therefore must determine 'whether the polic[ies]' definition of 'pollutant' applies unambiguously to' the noxious odors identified in the [underlying] Complaint.").

Our Court's line of cases is, moreover, consistent with Pennsylvania's broader approach of permitting an insurer to rely on an underlying complaint to demonstrate that other types of policy exclusions apply. *Cf., e.g., Mut. Ben. Ins. Co. v. Haver*, 725 A.2d 743, 746 (Pa. 1999) ("[W]e must determine whether the factual allegations in the complaint fall within the knowing endangerment

exclusion to coverage that is contained in the policy.”); *Humphreys v. Niagara Fire Ins. Co.*, 590 A.2d 1267, 1272 (Pa. Super. Ct. 1991); *Air Prods. & Chems. v. Hartford Accident & Indem. Co.*, 25 F.3d 177, 180 (3d Cir. 1994) (concluding that evidence “extrinsic” to the underlying complaints is unnecessary to determine that a policy exclusion applies).

C

So, the Court is obligated to address the central question presented by the motions; namely, whether the policies’ definition of “pollutant” applies unambiguously to EtO as alleged in the underlying actions. Again, the policies define the term “pollutant” as follows:

45. Pollutants means any solid, liquid, gaseous, or thermal irritant or contaminant, including smoke, vapor, soot, fumes, acid, alkalis, chemicals, and waste. Waste includes materials to be recycled, reconditioned, or reclaimed.

The underlying class-action complaint alleges that “EtO is a powerful cancer-causing gas” and that “the United States Environmental Protection Agency (EPA), the National Toxicology Program, the World Health Organization (WHO), and the International Agency for Research on Cancer (IARC) all classify EtO as a known human carcinogen.” First Am. Decl. J. Compl. Ex. 4 at 2, ECF No. 21-4. The complaint further alleges that:

EtO is one of 187 pollutants that EPA has classified as ‘hazardous air pollutants,’ also called ‘air toxics.’ It is dangerous, toxic, carcinogenic, and mutagenic. EtO is highly reactive, readily taken up by the lungs, efficiently absorbed into the blood stream, and easily distributed throughout the human body. Its deleterious properties have been widely known for decades.

Id. at 6. Likewise, the individual actions describe EtO as “a chemical that is toxic, ultrahazardous, and a known human carcinogen.” First Am. Decl. J. Compl. Ex. 5 at 7, ECF No. 21-5. Those complaints further allege that, “[s]ince as early as 1994, IARC [the “International Agency for Research on Cancer”] has considered EtO to be in the highest risk category: Group 1 (carcinogenic

to humans)” and “[a]ccording to the U.S. Environmental Protection Agency (“EPA”), EtO is carcinogenic to humans by the inhalation route of exposure.” *Id.* at 16.

At this time, after carefully comparing those averments with the definition of the term “pollutant” in the policies, which includes “any . . . irritant,” the Court concludes that the exclusion’s definition of pollutant clearly and unambiguously encompasses the substance known as EtO. *Cf. Madison Const. Co. v. Harleysville Mut. Ins. Co.*, 735 A.2d 100, 108 (Pa. 1999); *Travelers Prop. Cas. Co. of Am. v. Chubb Custom Ins. Co.*, 864 F. Supp. 2d 301, 315 (E.D. Pa. 2012). And, as the underlying complaints plainly aver that the underlying plaintiffs’ alleged injuries would not have occurred but for Braun’s discharge of EtO into the Allentown atmosphere, the Court concludes that the underlying complaints clearly and unequivocally trigger the pollution exclusions’ remaining causation requirement.

D

Lastly, to avoid the application of the pollution exclusions, Braun asserts that an exception to the exclusion applies. Again, the policies provide that the exclusion does not apply where, among other things:

Your Product or Your Work was cleared by any government health authority or regulatory body for marketing with a specific indication for medical, diagnostic, or therapeutic use[.]

In an attempt to invoke this exception, Braun points to two exhibits attached to its First Amended Answer and Counterclaim: (1) a permit issued by the Department of Environmental Protection (“DEP”) of the Commonwealth of Pennsylvania; and (2) U.S. Food and Drug Administration (“FDA”) correspondence clearing Braun to market certain medical devices. First Am. Answer & Countercl. Exs. F, G, ECF Nos. 31-6, 31-7. Noetic does not challenge the authenticity of these exhibits.

After reviewing those documents, the Court concludes that, construed in the light most favorable to Braun, neither exhibit supports the notion that a government health authority or regulatory body cleared EtO, or Braun's process of sterilizing of devices with EtO, for "marketing with a specific indication for medical, diagnostic, or therapeutic use."¹ First, the DEP permit relates to the mere discharge of EtO. It does not, in any way, relate to the marketing of EtO with a specific-use indication. Second, although the FDA's clearance letters relate to the marketing of various medical devices for specific uses, they clearly do not approve of the marketing of EtO itself or the marketing of Braun's sterilization processes. Since Braun must demonstrate that the clearance exception applies, *Air Prods. & Chems. v. Hartford Accident & Indem. Co.*, 25 F.3d 177, 180 (3d Cir. 1994), and as Braun has not offered any evidence, either from the complaints themselves or from external sources, showing that Braun was approved to market EtO or its process of sterilizing devices with EtO, the Court concludes that the pollution-exclusion exception does not apply.

IV

Consequently, Noetic has no duty to defend Braun in the underlying actions. The Court will enter judgment in favor of Noetic on Noetic's declaratory-judgment counts. It follows that the Court will also enter judgment in favor of Noetic on Braun's counterclaims. An appropriate order follows.

¹ Braun defines EtO as "Your Product" and the sterilization of devices with EtO as "Your Work." See Defs. Cross-Mot. For J. on the Pleadings at 25-26, ECF No. 41-1.